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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/812,884 | 03/21/2001 | Russell John Mumper | 50229-262 | 1135 |

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| EXAMINER | |
|---|---|
| YOUNG, MICAH PAUL | |
| **ART UNIT** | **PAPER NUMBER** |
| 1618 | |

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/812,884 | MUMPER ET AL. | |
| | Examiner | Art Unit | |
| | Micah-Paul Young | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 4/15/05.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21-30 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The process by which a solid is obtained from the essential components is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The present invention is drawn to a method of obtaining a solid nanoparticle product however, prior art has recognized the same components being used and manufactured in an identical way to that of applicant as not resulting in a solid form. Specifically Yiv et al USPN 6,245,349. The Yiv reference discloses an oil-in-water microemulsion that is heated and cooled at room temperature. The resultant product has very small particle sizes below 50 nm. The formulation comprises phospholipids, fatty acids and fatty alcohols, surfactants and molecules of interests, however after the cooling step an oil droplet is formed and not a solid nanoparticle as recited by applicant. Applicant recites in examples 6-17, that an emulsified wax is used as the nanoparticle matrix material, yet the claims are broadly drawn to a wide range of compounds such as al phospholipids, fatty acids and fatty acid alcohols in addition to emulsifying waxes. Applicant lists these compounds as interchangeable, yet when they are used by the Yiv reference an allegedly materially different product arises. Applicant is invited to provide an explanation to

this phenomenon. It is confusing to the Examiner how the same components can be used in the same way to achieve two different compounds. Further explanation is required. Until such explanation is receive the art rejections will remain.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 21-23, 25-27 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Yiv et al (USPN 6,245,349 hereafter '349). The claims are drawn to a process of making nanoparticles comprising making an oil-in-water microemulsion, by heating a nanoparticle mixture comprising a surfactant and a molecule of interest.

2. The '349 patent discloses method of making a nanoparticle drug delivery composition comprising heating an oil-in-water microemulsion to liquify it (col. 4, lin. 35-44). The

composition is stored at room temperature and is stable at such temperatures (*Ibid.*). The resultant diluted formulation comprising surfactants phospholipids, and polyoxyethylene derivatives (col. 6, lin. 12 – 24). The diluted formulation has an average particle size below 10 nm (col. 5, lin. 9). The formulation comprises water at a concentration of 95% (example1, table1). These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 24, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Yiv et al (USPN 6,245,349 hereafter '349). The claims are drawn to a method of making nanoparticles.

As discussed above the '349 patent discloses a method of making a nanoparticle composition comprising heating and cooling a microemulsion comprising surfactants and drug

molecules. The reference however differs in that it does not disclose the concentrations as recited in the claims. However, the reference does disclose each an every component of the formulation along with its steps. It is the position of the examiner that such limitations do not impart patentability to the claims in view of the prior art disclosures. The general conditions of the claims have been met, and applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

6. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

7. With these things in mind it would have been obvious to manipulate, and maximize the concentrations of the '349 reference in order to optimize the results. One of ordinary skill I the art would have been motivated to do so in order to obtain an optimal drug delivery composition. It would have been obvious to follow the suggestions of '349 patent with an expected result of a stable nanoparticulate drug delivery composition.

***Response to Arguments***

8. Applicant's arguments with respect to claims 21-30 have been considered but are moot in view of the new ground(s) of rejection. However as discussed in the 112 rejection, applicant has

claimed a process and product containing identical components to that of Yiv however the product is materially different from that of Yiv. Explanation is required on this point. It is confusing to the examiner how the same components, combined in the same way can result in different final products. Until such explanation is provided the claims will remain rejected over the closest art.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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